

**REMARKS**

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futagawa et al. (U.S. Patent No. 5,899,889) (hereinafter: "Futagawa") in view of Grippi et al. (WO 02/102571) (hereinafter: "Grippi").

The Office's position in this rejection is that it would have been obvious to one of ordinary skill in the art to replace the barrel of the prefilled syringe of Futagawa with a barrel as disclosed in Grippi having a multilayer structure in which an innermost layer and an outermost layer are both made of a polyolefin resin, and an intermediate layer is sandwiched by the innermost layer and the outermost layer and is composed of at least one layer made of a resin excelling in a barrier property. The motivation stated by the Office for such replacement is to inhibit the passage of atmospheric gases through the polymer wall of the barrel.

Applicants respectfully submit that a person of ordinary skill in the art would not have been motivated to modify the prefilled syringe of Futagawa as proposed in the Action because the medicament of the prefilled syringe of Futagawa is contained in a plastic tubular container provided in the prefilled syringe and is not in direct contact with the barrel of the syringe. Therefore,

the barrel of the prefilled syringe of Futagawa is not required to include an innermost layer having a barrier property.

Additionally, the proposed modification of the syringe of Futagawa will not result in the prefilled syringe of the present invention because the prefilled syringe of Futagawa does not include a gasket inserted adjacent to the open proximal end of the barrel in a fluid-tight manner as required by the claims of the present application. A fluid-tight gasket is not required in Futagawa because the medicament, as noted above, is contained in a plastic tubular container provided in the prefilled syringe. Futagawa discloses that the plunger of the syringe disclosed therein may be provided with an O-ring. It is clear, however, that the O-ring does not function as a gasket inserted adjacent to the open proximal end of the barrel in a fluid-tight manner. (See, for example, Col. 6, lines 47-50, of Futagawa).

For the above reasons, the 35 U.S.C. § 103(a) rejection is improper and should be removed.

Notwithstanding the impropriety of the 35 U.S.C. § 103(a) rejection, claim 1 has been amended to include the limitations of claims 2 and 4. More specifically, claim 1 has been amended to require that the intermediate layer is formed up to a vicinity of a surface of the tip of the luer tip, and is not formed in a direction of the proximal end of the barrel from a proximal end of

an initial insertion position of the gasket inserted in the barrel. In light of the amendments to claim 1, claims 2 and 4 to 6 have been canceled and claim 3 has been rewritten in independent form.

Futagawa and Grippi do not disclose and do not suggest an intermediate layer which is formed up to a vicinity of a surface of the tip of a luer tip of a prefilled syringe, and is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of a gasket inserted in the barrel.

In the present invention, securing of the barrier property of the barrel is ensured by forming the intermediate layer up to the vicinity of the luer tip surface (see paragraph [0020] of the specification of the present application). If the intermediate layer is exposed at the luer tip surface, the medication and the luer tip surface are at a high risk of coming into contact with each other, so that the polymer which composes the intermediate layer will be eluted into the medication, which should be avoided. Further, the intermediate layer is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel because the medication does not exist in the space from the proximal end of the gasket to the proximal end of the barrel (see paragraph [0022] of the specification of the present application).

Grippi discloses nothing concerning the specific structure of a multilayer syringe.

Moreover, neither Futagawa nor Grippi discloses, and the combination thereof does not suggest, a prefilled syringe having a multilayer structure in which an innermost layer and an outermost layer are both made of a polyolefin resin, and an intermediate layer is sandwiched by the innermost layer and the outermost layer and is composed of at least one layer made of a resin excelling in a barrier property, and wherein an end of the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion; the shoulder portion formed with the polyolefin resin has a thickness sufficient to exert a barrier property; and the luer tip is sealed by a cap having a barrier property.

Removal of the 35 U.S.C. 103(a) rejections of the claims is believed to be in order and is respectfully requested.

Rejoinder of withdrawn claims 7 and 8 is believed to be in order and is respectfully requested. Claims 1 and 3, which are now believed to be in condition for allowance, are directed to a product. Withdrawn claims 7 and 8 are directed to a process and recite a dependency on claim 1. According to the provisions of MPEP 821.04, process claims that depend from or otherwise include

all the limitations of the allowable product claims will be entered as a matter of right.

The foregoing is believed to be a complete and proper response to the Office Action dated November 16, 2005, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

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